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1103326-0503



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No: 6,858,645 B2  
Issued: February 22, 2005  
Name of Patentee: Nyqvist et al.  
Title of Invention: TARTRATE SALTS OF (R)-3-N,N-DICYCLOBUTYLAMINO-8-  
FLUORO-3,4-DIHYDRO-2H-1-BENZOPYRAN-5-CARBOXAMIDE  
Serial No.: 09/077,718  
Examiner: T. Solola  
Art Unit: 1626

Certificate  
MAR 03 2005  
of Correction

|   |                   |
|---|-------------------|
| CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8  |                   |
| I hereby certify that this paper is being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. |                   |
| <u>Andrew Fessak</u>  | <u>48,528</u>     |
| Agent Name  | PTO Reg. No.      |
| <u>Andrew Fessak</u>  | <u>2/25/2005</u>  |
| Signature   | Date of Signature |

Certificates of Correction Branch  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT  
FOR PTO MISTAKE [37 C.F.R. §1.322(a)]

1. It is noted that printing errors appear in the referenced patent which are attributable to the Office.
2. The location where the error(s) is/are shown correctly in the application file is:

MAR 9 2005

| Column and Line Number of Issued Patent                                  | Location in Application File Where the Error is Shown Correctly |
|--|---|
| Col. 6, line 13<br>"8-3,4-dihydro" should read --8-fluoro-3,4-dihydro--. | Amendment filed July 7, 2004<br>Former claim 3, page 2          |
| Col. 6, line 14<br>"(2R3R)" should read --(2R,3R)--.                     | Amendment filed July 7, 2004<br>Former claim 3, page 2          |

3. Attached is a copy of Form PTO/SB/44 (also Form PTO-1050).
4. Please send the Certificate to the undersigned Agent.
5. Patentees request that the issuance of a Certificate of Correction be expedited in accordance with the PTO's policy for expediting issuance of Certificates of Correction, as outlined in the PTO notice, issued August 21, 2002 entitled "Expedited Issuance of Certificates of Correction when the Error is Attributable to the United States Patent and Trademark Office". In support of the requested corrections, Patentees are attaching copies of the relevant pages from the application file with this Request.
6. No fee should be due in connection with this communication. However, if a fee is deemed to be due, the Commissioner is authorized to charge such fee to Deposit Account No. 23-1703.

Dated: Feb. 25, 2005

Respectfully submitted,

Andrew Fessak

Andrew Fessak- Reg. No. 48,528  
Customer No. 007470- White & Case LLP  
Direct Line: (212) 819-8437

Enclosures

MAR 9 2005

# UNITED STATES PATENT AND TRADEMARK OFFICE

## CERTIFICATE OF CORRECTION

Patent No: 6,858,645 B2  
Issued: Feb. 22, 2005  
Name of Patentee: Nyqvist et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 6

Line 13: "8-3,4-dihydro" should read --8-fluoro-3,4-dihydro--.

Line 14: "(2R3R)" should read --(2R,3R)--.

MAILING ADDRESS OF SENDER:

Andrew Fessak  
White & Case LLP  
1155 Avenue of the Americas  
New York, New York 10036

Burden Hour Statement: This form is estimated to take 1.0 hour to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

(Certificate of Correction (PTO/SB/44) [14-3]—page 1 of 1)



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Nyqvist et al.  
 Serial No. : 09/077,718  
 Filed : June 8, 1998  
 For : TARTRATE SALTS OF (R)-3-N,N-DICYCLO-  
 BUTYLAMINO-8-FLUORO-3,4-DIHYDRO-  
 -2H-1-BENZOPYRAN-5-CARBOXAMIDE  
 Examiner : T. Solola  
 Group Art Unit : 1626

|   |                    |
|---|--------------------|
| <b>CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. 1.8</b>  |                    |
| I hereby certify that this paper is being facsimile transmitted to the U.S. Patent and Trademark Office on the date indicated below at the facsimile number <u>703-872-9306</u> . |                    |
| <u>John M. Genova</u>   | <u>32,224</u>      |
| Agent Name  | PTO Reg. No.       |
| <u>John M. Genova</u>   | <u>7 July 2004</u> |
| Signature   | Date of Signature  |

**Mail Stop RCE**

Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

**ATTENTION: Examiner T. Solola**  
**DATE: 7 July 2004**  
**NUMBER OF PAGES: 8 (including PTO/SB/30)**  
**FAX NUMBER: 703-872-9306**

**AMENDMENT**

Sir:

Applicant submits this Amendment in response to the final Office Action, mailed November 19, 2003. A Request for Continued Examination ("RCE") is being submitted concurrently under separate cover.

A Notice of Appeal was filed on May 14, 2004. Therefore, this Amendment and the RCE are timely as being submitted within two months of the filing date of the Notice of Appeal.

**Prior to further examination, please amend the above-identified application as follows:**

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

**Remarks** begin on page 4 of this paper.

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### **Amendments to the Claims**

**This listing of claims will replace all prior versions and listing of claims in the application.**

Claims 1-2 (Canceled)

3. (Original) The salt (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-1-benzopyran-5-carboxamide hydrogen (2R,3R)-tartrate monohydrate.

4. (Previously presented) The salt according to claim 3 in crystalline form.

5. (Previously presented) A pharmaceutical formulation containing, as active ingredient, the salt according to claim 3 or 4 in association with a suitable diluent, excipient or an inert carrier.

Claims 6-11 (Canceled)

12. (Currently amended) A method for the ~~[prevention or the]~~ treatment of **a condition selected from the group consisting of depression and anxiety** ~~[CNS disorders and related medical disturbances]~~ comprising administration, to a host in need of such treatment, an effective amount of the salt according to claim 3 or 4.

13. (Canceled)

14. (Currently amended) **The** [A] method according to claim **12, wherein the condition is** ~~[13 for the prevention or the treatment of]~~ depression.

15. (Currently amended) The [A] method according to claim 12, wherein the condition is [13  
~~for the prevention or the treatment of~~] anxiety.

16. (Currently amended) A process of making the salt as defined in claim 3 or 4 which comprises the following consecutive steps:

- i) dissolving (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-1-benzopyran-5-carboxamide in an organic [~~appropriate~~] solvent, optionally by heating,
  - ii) adding (2R, 3R)-tartaric acid dissolved in an [~~appropriate~~] aqueous organic solvent or non-aqueous organic solvent,
  - iii) allowing the solution obtained to stand cold to crystallize,
  - iv) optionally recrystallizing in an [~~appropriate~~] aqueous organic solvent, if a non-aqueous organic solvent is used in step ii),
- to obtain the salt defined in any one of claims 3 or 4.

17. (Currently amended) A process of making the salt as defined in claims 3 to 4 which comprises [~~a final step of~~] recrystallizing (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-benzopyran-5-carboxamide hydrogen (2R, 3R)-tartrate in an [~~appropriate~~] aqueous organic solvent.

18. (Currently amended). The [A] process according to claim 16 or 17, wherein the aqueous organic solvent is aqueous acetone.

Claims 19-20 (Canceled)

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